Exhibit C

IN THE UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE
DIANNE M. BELLEW, Plaintiff,	
-vs-	No. 13-CV-22473
ETHICON, INC., ET AL., Defendants.	

VIDEOTAPED DEPOSITION OF

DENISE M. ELSER, M.D.

September 16, 2014

Chicago, Illinois

of that mesh kit in a woman's body?

A. I've never thought an IFU would tell me every risk.

Q. Well, as you sit here now do you have an understanding of any standard whatsoever from any source as to what risks and complications are supposed to be disclosed in an IFU?

A. No.

MR. COMBS: Object to the form.

BY MR. SLATER:

Q. When you're giving your opinions as to whether or not the IFU adequately warns of risks and complications, you're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair?

A. That's fair.

Q. You're not relying on any objective standard from any source, correct?

A. Correct.

Q. And you're not corroborating your -- rephrase.

Have you made any effort to corroborate your own opinion as to what needs to be in a warning in an IFU by looking to what Ethicon's professionals believed needed to be in there just

so you could see whether the standard you were applying was consistent with what someone in the medical device industry would apply? Did you ever do that?

A. No.

MR. COMBS: Object to form.

BY MR. SLATER:

Q. Are you aware of whether there are FDA regulations which provide for what type of information is supposed to be provided in an IFU?

A. No.

Q. Have you looked at any internal documents at all, whether it's an e-mail, whether it's a deposition, anything, from Ethicon or any testimony from anyone in Ethicon, regarding what FDA regulations would require to be disclosed in an IFU?

A. No.

Q. Have you made any effort before today to find out what FDA regulations require a medical device company to disclose in an IFU?

A. No.

Q. Earlier you told me what you expected to see in an IFU. That's -- is it fair to say that's the standard you applied as to what you think needs

to be disclosed in an IFU?

MR. COMBS: Object to form.

BY THE WITNESS:

A. Yes.

BY MR. SLATER:

Q. In terms of whether or not Ethicon adequately warned, if it turns out that Ethicon had information, which if you applied Ethicon's own warning standards, the standards that their medical people said they were applying and the Regulatory Affairs people said they were applying, and if Ethicon failed to provide that information, would you agree that would be a failure to provide an adequate warning?

MR. COMBS: Object to form.

BY THE WITNESS:

A. No, because I have no idea what their Regulatory Affairs department would think was adequate and whether that was clinically relevant to what I'm doing in surgery.

BY MR. SLATER:

Q. Your background and experience is not necessarily the same as other doctors who use medical devices, correct?

A. Correct.

BY THE WITNESS:

A. No, I'd like to think that my standards would be fairly applicable to a pelvic floor reconstructive surgeon.

BY MR. SLATER:

Q. What have you ever done to confirm that your standard for what needs to be in an IFU -- well, rephrase.

Have you ever studied the question of what information needs to be in an IFU? Have you ever engaged in any study of that question?

A. No, I have not.

Q. Have you ever made any effort to confirm that your understanding for what needs to be in an IFU is consistent with what other doctors believe should be in an IFU? Have you ever studied that question?

A. No, I have not.

Q. As you sit here now you don't know whether or not the standard you're applying for what needs to be in an IFU is consistent with what other doctors think. You don't know that because you've never tried to verify that, correct?

MR. COMBS: Object to form.

BY THE WITNESS:

A. No, but not studying something formally does not mean I haven't discussed IFUs with other similar physicians who have similar practices and take care of patients who need prolapse repairs.

MR. SLATER: Move to strike after the word "no."

BY MR. SLATER:

Q. In doing your work in this case were you curious as to what the Regulatory Affairs department in Ethicon who are the professionals who are required to make sure that an IFU complies with FDA regulations, were you curious what they thought needed to be in an IFU?

MR. COMBS: Object to form.

BY THE WITNESS:

A. No, I was not.

BY MR. SLATER:

Q. You have not reviewed any Ethicon internal documents other than those few that you listed for me, correct?

A. Not that I recall right now related to this case.

Q. Is it fair to say you have no idea what complications and risks were known to Ethicon Medical Affairs and when they were known?

A. That would be fair.

Q. Would you agree with me that if Ethicon Medical Affairs knew there was a potential risk or complication attributable to the Prolift mesh implant itself which if it occurred could cause severe permanent injury to a woman, that that risk should be disclosed in the IFU? Would you agree with that statement?

MR. COMBS: Object to form.

BY THE WITNESS:

A. No, I don't think it necessarily needs to be in the IFU.

BY MR. SLATER:

Q. Have you ever studied the question of what risks and complications were known to doctors across the country with various backgrounds and levels of experience with regard to the use of the Prolift? Did you ever study that question?

A. No.

Q. And you don't know the answer to that question, correct?

A. Correct.

Q. One of the references in your article is the Blandon article from some doctors at the Mayo Clinic, correct?

since from your perspective Ethicon didn't need to warn of any risks anyway so whatever they put in there is more than they needed to do anyway?

MR. COMBS: Object to the form.

BY MR. SLATER:

Q. Do I understand you?

A. Yeah, and they did have warnings about the complications.

Q. Do I understand -- so I understand your opinion, correct?

A. Correct.

Q. I'm going to ask you a different question now relating back to what you asked me.

Once the IFU is out there, if Ethicon learned of a risk or a complication that was not previously warned about and it was a significant risk or complication in terms of the harm it could cause to a woman, do you know whether or not Ethicon had any obligation or have any opinion whether they had any obligation to get that information out to doctors?

A. I don't know what the obligations are. So, do they get -- would it be updated on a regular time interval or is it depending on when complications happen?

Q. Again, in forming your opinions, you don't know what Ethicon's obligations were to warn, correct?

A. Correct.

Q. So, your opinions are not based on what Ethicon was obligated to do from any source, right?

MR. COMBS: Object to the form.

BY THE WITNESS:

A. I -- my opinion is that as a surgeon who has -- who does pelvic reconstructive surgery and using mesh that what I expect the company put in the IFU to help me understand how to do pelvic reconstructive surgery with mesh may not include every single complication.

MR. SLATER: Move to strike.

BY MR. SLATER:

Q. All I'm saying is the opinions you're offering about the warnings are not based on any standard whatsoever as to what Ethicon was required to do because you don't know what they were required to do, right?

A. No, I'm commenting on what the average pelvic surgeon needs to know.

MR. SLATER: Move to strike.

BY MR. SLATER: